



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

October 14, 1993

MEMORANDUM

SUBJECT: Interpretation of the Good Laboratory Practice (GLP)
Regulation

GLP Regulations Advisory No. 66

FROM: David L. Dull, Director
Laboratory Data Integrity Assurance Division

TO: GLP Inspectors

Please find attached an interpretation of the GLP regulations as issued by the Policy & Grants Division of the Office of Compliance Monitoring. This interpretation is official policy in the GLP program and should be followed by all GLP inspectors.

For further information, please contact Francisca E. Liem at FTS-398-8265 or (703) 308-8265.

Attachment

cc: M. Stahl
C. Musgrove



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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Dear

This is in response to your letter of August 27 1993 to Dr David Dull in which you requested clarification regarding the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) Good Laboratory Practice Standards (GLPS) That letter was referred to me for reply

Specifically you requested clarification regarding Advisories 52 and 59. You felt that the two Advisories presented conflicting interpretation regarding whether a Quality Assurance Unit (QAU) for a study could belong to the company that the study director of that study is president of. You felt that Advisory 52 suggests that such situations are acceptable while Advisory 59 suggests otherwise.

The conflict which you perceive to exist between Advisories 52 and 59 may result from a misinterpretation of Advisory 52 This advisory includes a statement to the effect that a study director/company president arrangement is not inherently violative of GLPS. This is true since there are no specific regulatory prohibitions against it and it is normally possible to deal with compliance issues that arise under such an arrangement For example, if the QAU's independence is compromised, a solution could be for the sponsor to supply the QAU or contract a QAU from outside the facility

Although a study director/company president arrangement is thus not always violative it may nevertheless be violative if QAU independence or other specific conflicts with management responsibilities are not dealt with. Advisory 59 provides an example of one scenario, i.e., where the company president is the study director and performs all management duties including overseeing the QAU in which this type of arrangement causes definite problems.

Please note that advisories generally originate as written GLP-related communications With persons outside EPA The Agency makes the content of such communications available as advisories in the interest of improving the understanding of the entire regulated community with respect to a particular policy advisement However any guidance contained in such a communication is intended to apply to a specific situation. Misunderstandings may occur if guidance contained in an advisory is applied to a situation different from

that which the original communication addressed. Where general policy guidance is intended it is released in the form of documents intended specifically for that purpose such as the Good Laboratory Practice Standards (GLPS) Questions and Answers Document of May 14 1992

If you have any questions concerning this response please contact Steve Howie of my staff at (703) 308-8290.

Sincerely yours,

/s/John J. Neylan III, Director,
Policy and Grants Division
Office of Compliance Monitoring(EN-342)

cc: David L. Dull
GLP File